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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,123	06/22/2006	Hermann Gohl	07552.0056	1075
22852	7590	11/26/2008		
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER STEELE, JENNIFER A	
			ART UNIT	PAPER NUMBER
			1794	
			MAIL DATE	DELIVERY MODE
			11/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/540,123

Applicant(s)

GOHL ET AL.

Examiner

JENNIFER STEELE

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-21 and 24-27 is/are pending in the application.
- 4a) Of the above claim(s) 8-19, 26 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-7, 20-21, 24-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claim 1, 3, 5-7, 20-21 and 24-25 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over EP 0568045.

Claim 1 describes a permselective asymmetric hollow fiber membrane suitable for hemodialysis comprising:

- at least one hydrophobic polymer and
- at least one hydrophilic polymer
- wherein said hollow fiber membrane has a four layer structure comprising
 - a first inner separation layer in the form of a dense rather thin layer
 - a second layer in the form of a sponge structure
 - a third layer in the form of a finger structure

- and a fourth outer layer in the form of a sponge layer having an outer surface having pores with sizes in the range of 0.5-3 micron, the number of said pores on the outer surface of the sponge layer being in the range of 10,000 to 150,000 pores per mm^2

EP '045 teaches a polysulfone hollow fiber membrane with an inner dense skin layer composed of polysulfone and a lesser amount of polyvinylpyrrolidone. A polysulfone is a hydrophobic polymer and the polyvinylpyrrolidone is a hydrophilic polymer as taught in Applicant's own specification [0032] and [0033]. EP '045 teaches hollow fiber membranes are asymmetrical (page 10, lines 46). EP '045 teaches dense skin layer on the inner surface of 0.1-3 micron thick for separating substances from filtrates which contains micropores having a pore diameter gradually increasing toward a core layer supporting the skin layer (page 10, lines 47). This structure where the pores gradually increase is equated with the second layer in the form of a sponge structure. EP '045 teaches a supporting core layer of reticular texture having micropores of a 1-5 micron average pore diameter and this layer is equated with Applicants third layer of a finger structure as a finger would be reticular structure.

EP '045 teaches outer surface layer of reticular texture having micropores of a 0.1-0.5 micron average pore diameter on the outer surface, as the ranges overlap at 0.5 micron average pore diameter (page 10, lines 44-51). EP '045 shows the structure of the outer surface layer of the polysulfone-based hollow fiber membrane in Fig. 1 which shows that there is a number of pores present, however EP '045 differs and does not teach the number of pores present on the outer surface. EP '045 further teaches the

process conditions can be modified to optimize the outer surface structure. EP '045 teaches a dry-jet-wet spinning process wherein extrudates pass through a gaseous atmosphere, generally air, during traveling from the outlet of the orifice to the coagulating bath which is called the "dry zone". When the "dry zone" is humidified, the moisture in air may promote microphase separation whereby hollow fiber membranes having many micropores of relatively large diameter in their outer surface can be readily obtained. EP '045 presents a finding that one of ordinary skill in the art could optimize the process conditions to obtain the desired pore size and number of pores on the surface with a reasonable expectation of success.

As to claim 3, EP '045 differs and does not teach the property of diffusive permeability. As EP '045 teaches the same structure and materials as the claimed invention, it is presumed that the property of diffusive permeability is inherent to the structure of EP '045.

As to claim 5, EP '045 teaches the membrane has a composition of hydrophobic polymer of to hydrophilic polymer in the range of 90% hydrophobic and 10% hydrophilic and 60% hydrophobic and 40% hydrophilic which encompasses the claim ranges of 65-95% hydrophobic polymer and 5-35% hydrophilic polymer.

As to claim 6, EP '045 teaches the hydrophobic polymer is polysulfone which is equated with polysulphone.

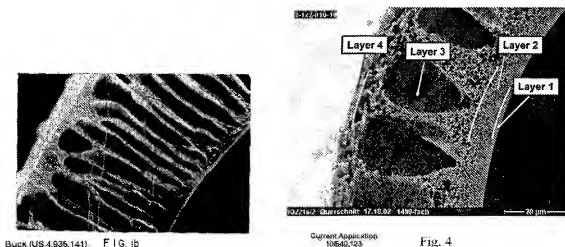
As to claim 7, EP '045 teaches the hydrophilic polymer is polyvinylpyrrolidone.

As to claims 20 and 21, EP '045 teaches the membranes are for use for hemodialysis, hemofiltration and hemoconcentration.

As to claim 24 and 25, EP '045 differs and does not teach the number or density of pores on the outer surface. EP '045 further teaches the process conditions can be modified to optimize the outer surface structure. EP '045 teaches a dry-jet-wet spinning process wherein extrudates pass through a gaseous atmosphere, generally air, during traveling from the outlet of the orifice to the coagulating bath which is called the "dry zone". When the "dry zone" is humidified, the moisture in air may promote microphase separation whereby hollow fiber membranes having many micropores of relatively large diameter in their outer surface can be readily obtained. EP '045 presents a finding that one of ordinary skill in the art could optimize the process conditions to obtain the desired pore size and number of pores on the surface with a reasonable expectation of success.

2. **Claim 1 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Buck (US 4,935,141).** Buck teaches a permeable asymmetric membrane preferably in the shape of hollow fibers (ABST). Buck teaches a three layer membrane with a dense inner layer of thickness of less than 1 micron, a second sponge layer with a thickness of 5 micron and a third open finger like structure having a thickness of 20 to 60 micron. Buck shows the structure in Fig. 1b. Buck differs from the current application and does not teach a fourth layer in the form of a sponge layer having an outer surface with pores sizes in the range of 0.5-3 micron. However, side-by-side comparison of the photomicrographs of Buck '141 and the current application indicates that the prior art to Buck has the same structure as the

current application. As shown in the figures below, with prior art of Buck '141 on the left and the current application on the right, Examiner presumes that the structure of Buck has the stated properties of an outer surface is sponge-like with a pore size of 0.5 to 3 micron and that the structure of Buck '141 anticipates the current application. When the reference discloses all the limitations of a claim except a property or function, and the examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention the examiner has basis for shifting the burden of proof to applicant as in *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See MPEP § 2112- 2112.02



3. Claim 4 rejected under 35 U.S.C. 103(a) as obvious over EP 0568045 in view of Buck (US 4,935,141) and Maeda et al (US 5,707,522).

As to claim 4, EP '045 teaches the membrane can have a total membrane thickness of 5 to 250 micron. EP '045 teaches a first inner separation layer has a

thickness of 0.1 to 3 micron thick and in the claimed range of less than 1 micron. EP '045 differs from the current application and does not teach the layer thickness of the second, third and fourth or outer layer.

Buck teaches a selectively permeable asymmetric membrane suitable for use in hemodialysis and processes for manufacturing such membranes (Title). Buck teaches the membranes are preferably formed in the shape of hollow fibers (ABST). Buck teaches a three layer membrane with a dense inner layer of thickness of less than 1 micron, a second sponge layer with a thickness of 5 micron and a third open finger like structure having a thickness of 20 to 60 micron. Buck shows the structure in Fig. 1b.

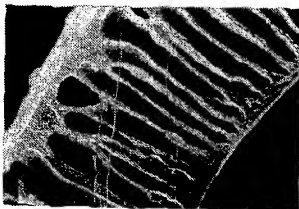


FIG. 1b

Maeda teaches a permselective membrane that is comprised of a hollow fiber asymmetric membrane having an outermost layer of a dense skin layer having a thickness of 0.05 to 5 micron and is characterized as having pore sizes of at least 0.5 micron (col. 3, lines 19-25).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to produce a permselective asymmetric hollow fiber membrane with

the layer thicknesses as claimed motivated to produce a membrane with the desired properties of permeability and selectivity of permeable compounds.

Response to Arguments

4. Applicant's sent in replacement drawing sheet with amendments and the previous objection to the drawings has been withdrawn.
5. Applicant's arguments with respect to claim 1, 3-7, 20-21,24-25 have been considered but are moot in view of the new ground(s) of rejection. New 35 USC 103(a) rejection has been presented with reference to EP 0568045 as EP 0568045 teaches the same materials and a four layer structure.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER STEELE whose telephone number is (571)272-7115. The examiner can normally be reached on Office Hours Mon-Fri 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. S./
Examiner, Art Unit 1794

/D. Lawrence Tarazano/
Supervisory Patent Examiner, Art
Unit 1794

11/23/2008